In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 20-1099V

* *	Chief Special Master Corcoran
STEPHEN PEKA, *	
*	
Petitioner, *	Dated: March 7, 2024
*	
v. *	
*	
SECRETARY OF HEALTH AND *	
HUMAN SERVICES, *	
*	
Respondent. *	
*	
* *	

David John Carney, Green & Schafle LLC, Philadelphia, PA, for Petitioners.

Zoe Wade, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On August 28, 2020, Stephen Peka filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Program").[2] ECF No. 1. Petitioner alleges that an influenza ("flu") vaccine administered to him on October 9, 2018, caused him to develop a shoulder injury related to vaccine administration ("SIRVA")— a Table claim, and also alleges a causation-in-fact claim based on the same set of facts. The matter went to trial on June 21, 2023, followed by some post-hearing filings. *See* Petitioner's Brief, dated August 16, 2023 (ECF No. 55) ("Br."); Respondent's Brief, dated November 29, 2023 (ECF No. 64) ("Opp."); Petitioner's Reply, dated December 22, 2023 (ECF No. 68) ("Reply").

Now, having reviewed the record, trial testimony, expert reports, and other briefing, I find entitlement for Petitioner, for the reasons set forth below.

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[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

I. Factual Background

Pre-vaccination records filed in this case reveal that Petitioner had a prior history with arm pain and associated issues. For example, Petitioner had an x-ray of his left shoulder on August 4, 2015 for "left shoulder pain," and it showed mild degenerative changes of the acromioclavicular joint and rotator cuff calcification, suggestive of calcific tendinosis. Ex. 3 at 213. The following year, Petitioner complained of neck and wrist pain, and EMG testing revealed carpal tunnel syndrome, leading him to obtain treatment specific to that condition. *Id.* at 158, 165; Ex. 8 at 11–17. In 2017, Petitioner complained of morning joint stiffness. Ex. 3 at 136. And in the first half of 2018, Mr. Peka sought chiropractic care for back and neck pain that more often than not radiated into his shoulders and hands. Ex. 3 at 106–07, Ex. 6 at 17.

Vaccination and Initial Reports of Shoulder Pain

On October 9, 2018, Mr. Peka visited CentraCare Clinic in St. Cloud, MN, for a medication management appointment, and at this time he received a flu vaccine in his left shoulder. *See* Exs. 1, 2 at 2. Petitioner has alleged that he noticed the vaccine was administered too high in his arm, and that he immediately felt soreness and pain that persisted through the day. Ex. 2 at 2. The pain was so severe that he was barely able to raise his arm. *Id.* at 2–3.

Two weeks later (October 23, 2018), Petitioner saw Dr. Laura Mollenhoff at CentraCare Clinic, where he reported his left shoulder pain "since" the time of vaccination. Ex. 3 at 80. He characterized the pain as like a "bee sting." *Id.* He also stated that he had observed some redness near the injection site, and complained of some other symptoms not associated with a SIRVA (*e.g.,* chills and sweats). *Id.* Some skin irritation was observed by Dr. Mollenhoff, plus some swelling. *Id.* But an ultrasound showed nothing abnormal, and Mr. Peka's range of motion ("ROM") was normal as well. *Id*. at 79. Petitioner reported no improvement at a subsequent CentraCare visit on October 29, 2018. Ex. 3 at 73, 77. It was observed at this time by a treater that cellulitis had been suspected, and that the injection site still showed an injury, although some of the redness had resolved, and Petitioner again displayed normal ROM. *Id.* He was deemed to have pain associated with the vaccination, and was prescribed steroidal medication to treat arm inflammation. *Id*.

On November 15, 2018, Petitioner saw his primary care physician in association with diabetes treatment. Ex. 3 at 65. The record from this visit memorializes the fact that Petitioner had been seen a few weeks before for arm pain associated with a flu vaccine, among other things, but that "in the interim patient reports his symptoms have improved," with him now feeling to be "at his baseline." *Id.* Petitioner also reported that he saw an ENT specialist for a persistent nosebleed, that he was experiencing no other issues, and had no other questions or concerns to discuss that day. *Id.*

Ongoing Pain Reports in 2019

There is next an almost three-month treatment gap, with no evidence of additional medical visits of any kind until early February 2019. Petitioner now returned to CentraCare Clinic—and unquestionably complained of worsening left shoulder pain, which he again associated with the October vaccination. Ex. 3 at 61. He in fact stated he had felt an ache there "since" that time, and that movement caused the pain to increase. *Id.* The treater exam confirmed "pain with abduction left arm above shoulder level," and the treater speculated whether Petitioner "could have a partial rotator cuff injury." *Id.* at 64. An MRI performed thereafter (on February 18, 2019) was deemed to reveal tendinosis as well as some increased fluid in the subacromial/subdeltoid bursal space, among other things. *Id.* at 58–60.

The following month, Mr. Peka visited Hjort Chiropractic, reporting left shoulder pain that worsened when reaching out, up, or down. Ex. 6 at 53–54, 57. Thereafter, he returned to Hjort Chiropractic eighteen times for regular visits, consistently complaining of vaccine-related shoulder pain. *Id*. at 57–111.

Later on, in August 2019, Mr. Peka went again to CentraCare, and a treater who reviewed his February MRI deemed it to be "suggestive of partial tendon tear." Ex. 3 at 30. At this visit, the following comment was included in his exam notes: "Left shoulder: Limited range of motion with internal and external rotation, drop arm test positive. Tenderness with palpation." *Id*. at 29. This appears to be the first post-vaccination record in which abnormal ROM issues were documented—and it came about ten months post-vaccination.

Petitioner visited a St. Cloud orthopedic practice that same August, reporting localized shoulder pain since the October 2018 vaccination, as well as ROM limitations (albeit without specifying when they began). Ex. 4 at 5. A treater reviewed Petitioner's previous MRI scans, noting that they confirmed tendonitis and "increased signal in subacromial and subdeltoid bursa," and also found that ROM limitations were evident on exam. *Id.* at 6. The treater recommended that Petitioner be given a cortisone injection and begin physical therapy ("PT"). *Id*. at p. 6–7. Petitioner began PT the next month, continuing it for 10 sessions or until early December 2019. Ex. 5 at 10, 19-20. But he was unable to reduce his pain to the below-50 percent level that had been a goal. *Id.* at 10.

Petitioner has filed other medical records for treatment received in 2020 and thereafter in connection with this alleged shoulder injury. While these records do not bear particularly on the resolution of entitlement, they reflect Petitioner's persistent complaints about unabated shoulder pain.

II. Hearing Witnesses

A. Petitioner's Witnesses

1. *Stephen Peka*

Mr. Peka was the sole fact witness to offer testimony at trial. He testified that, prior to his injury, he underwent two cervical fusions. Tr. at 7. The first fusion was performed in 1983, and the second in 2007. *Id*. at 7–8. In total, seven of his neck vertebrae were fused together. *Id*. He did various therapies after these procedures, and continues to see a chiropractor regularly. *Id*. at 8, 12. He testified that his cervical spine issues are ongoing, but remain "steady," neither worsening nor improving. *Id*. at 14. Around 2000, he had surgery on his left wrist after an injury. Id. at 9. He then had a revision to that surgery in 2015, and follow-up therapy. *Id*. at 9–10. He stated that the wrist issues he had before the 2015 surgery have largely resolved. *Id*. at 10. He was able to resume active hobbies such as golfing and fishing. *Id*. In addition to these issues, he was diagnosed with pre-diabetes around 2000, which has been well-controlled with Metformin for around ten years. *Id*. at 12–13. He does not experience symptoms of his diabetes. *Id*.

Mr. Peka then testified about the day he received his flu vaccine. Tr. at 13. He had received it routinely for "decades," and normally got it in the fall. *Id.* at 14. This time, he "immediately felt a severely hard stinging, stabbing sensation" when the needle was inserted. *Id*. at 15. He also noted the needle was inserted higher on his shoulder than the normal "lower center shoulder" position. *Id*. He let the nurse administering the vaccine know about the pain, but says she insisted it was normal for a flu vaccine and would subside in a few days. *Id*.

As Mr. Peka drove home, he could not lift his left arm high enough to turn the steering wheel without "a lot of pain." Tr. at 15. At home, he "didn't do anything the rest of the day because it hurt that much." *Id*. at 16. Although he had felt discomfort after flu shots in the past, he testified it was "…nothing like this. This was adamantly different." *Id*. at 17. The injection site felt warm and swollen to the touch, and had red discoloration where the needle was inserted. *Id*. at 17–18. Eventually, he began taking oxycodone and hydrocodone pills prescribed for his cervical fusion. *Id.* at 18. Prior to the vaccination, he took these pills only one or twice a month. *Id*. at 19. He described his pain level that day as a 9 or 10 out of 10. *Id*. at 19–20.

Afterward, his shoulder pain continued after that day, giving him ROM issues. Tr. at 19. He had to compensate by using his right arm only for physical tasks, such as vacuuming or washing his hair. *Id*. He could not engage in any of his hobbies, and experienced poor sleep. *Id*. at 23. His shoulder was still swollen and warm to the touch after several days, prompting him to schedule a doctor's appointment. *Id*. at 22. At that appointment, he saw a nurse practitioner, who prescribed

him an antibiotic. *Id*. at 25. The antibiotic made him sick, and he did not remember whether he took the full course. *Id*. at 26. He returned to his physician's office on October 29, 2018, at which time a different nurse practitioner examined his shoulder, which was warm, swollen, and tender. *Id*. at 27–28. She prescribed Mr. Peka a steroid, and told him to ice his shoulder. *Id*.

Mr. Peka told his chiropractor (who normally treated him for cervical spine issues) about his shoulder pain during that month. Tr. at 29. The chiropractor did not work on his shoulder, as the cause of his pain had not yet been determined, but suggested that Mr. Peka consult with an attorney about a potential vaccine injury. *Id*. at 29–30. He gave Mr. Peka exercises for his shoulder to complete at home, and told him to ice the shoulder regularly. *Id*. at 31-32.

Mr. Peka was able to see his primary care physician, Dr. John Johnson, on February 8, 2019. Tr. at 32. Dr. Johnson performed ROM testing, during which Mr. Peka displayed "stabbing pain." *Id.* at 33. Dr. Johnson told Petitioner he suspected there was a tear in the shoulder, and ordered an MRI. *Id.* After the MRI was performed, Mr. Peka's chiropractor asked to see the results. *Id*. at 34. "He read the results and said that there was some fraying, a tear, and something like a fluid in there around the bursa." *Id*. Mr. Peka saw an orthopedist on October 23, 2019, who reported the same findings. *Id*. at 35. He was diagnosed with subacromial bursitis and rotator cuff tendonitis, and the orthopedist suggested he first try physical therapy before moving on to steroid injections or surgery. *Id.* at 35, 37.

Mr. Peka underwent 10–12 sessions of physical therapy, which was the most his insurance allowed. Tr. at 39. During these sessions, the therapist focused solely on his left shoulder. *Id*. These sessions helped him regain "a little bit" of ROM, but did not improve his pain. *Id*. He still could not use his left arm for household tasks, or engage in his normal hobbies. *Id.*

Through the end of 2022, Mr. Peka continued to have visits with various providers to address his shoulder issues, including his chiropractor and a massage therapist. Tr. at 40. The chiropractor performed trigger point work on his shoulder, and gave him exercises to do at home. *Id*. at 40–41. He was still unable to engage in physical hobbies like fishing and golf, and could not lift his grandchild. *Id*. at 41–42. Eventually he had surgery on his *right* shoulder, and underwent physical therapy. *Id*. at 43. He explained his ongoing left shoulder issues to his physical therapist, and they added in therapy exercises for his left shoulder during sessions. *Id*. These exercises included strength work, rotations, and taping. *Id.* at 44. He acknowledged that the work on his left shoulder was not documented much in the medical records, and opined that this was because the visits were prescribed for his right shoulder. *Id.* at 45.

Mr. Peka testified that his left shoulder had neither improved nor gotten worse at the time of the hearing. Tr. at 45. When he is at rest, it aches, but if the shoulder dangles it becomes painful.

Id. He cannot lift it above 90 degrees without pain. *Id.* He takes pain medication periodically, and continues to see his chiropractor regularly. *Id*. at 46.

2. *Naveed Mayer Natanzi, D.O.*

Dr. Natanzi, a board-certified specialist in physical medicine and rehabilitation, prepared a written report for Petitioner in support of the contention that the flu vaccine can cause SIRVA, and that it did so in this case within the medically acceptable timeframe. Report, dated July 26, 2022, filed as Ex. P16 (ECF No. 34-1) ("Natanzi First Rep."). He also testified at the hearing.

Dr. Natanzi received a Bachelor of Arts in Biological Studies at the University of California, Santa Barbara in 2007, and attended medical school at Western University of Health Sciences, where he received a Doctor of Osteopathy in June 2012. *Curriculum Vitae,* filed as Ex. P17 on July 26, 2022 (ECF No. 34-2) ("Natanzi CV") at 2. Dr. Natanzi completed an internship at Downey Regional Medical Center from 2012-2013, then completed his residency in physical medicine and rehabilitation at the University of California, Irvine from 2013-2016. Natanzi CV at 1–2. Dr. Natanzi completed a fellowship at the Bodor Clinic in Napa, California from January 2017-August 2017. *Id.* at 1. From 2017-2018, Dr. Natanzi worked at the Pasadena Rehab Institute as an attending physician specializing in interventional pain management. *Id*. In November 2017, Dr. Natanzi founded the Regenerative Sports and Spine Institute, and since April 2018, Dr. Natanzi has been a staff physician at the VA Long Beach Healthcare System. *Id.*; Natanzi First Rep. at 1. Dr. Natanzi is board certified by the American Academy of Physical Medicine and Rehabilitation and is board-eligible by the American Board of Pain Management. Natanzi CV at 1; Natanzi First Rep. at 1.

Dr. Natanzi began his testimony discussing his professional background, and his experience seeing patients with shoulder injuries after vaccination. Tr. at 52–55. He also explained the nature of SIRVA injuries, including clinical indicators and treatment options. *Id.* at 60–65.

Based on his review of Petitioner's records, Dr. Natanzi opined that Petitioner had experienced a SIRVA as a result of the flu vaccine. Tr. at 59. He pointed to several indicators of this injury in the records—"[i]mmediate onset of pain, signs of—use of the shoulder, protracted course of pain, these are the prongs we want to meet in establishing a SIRVA injury." Tr. at 81–82. He first noted that Petitioner had experienced pain immediately upon injection, which occurs in over half of SIRVA patients. *Id*. at 71; S. Atanasoff et al*., Shoulder Injury Related to Vaccine Administration (SIRVA)*, 28 Vaccine 8049, 8050 (2010), filed as P18(d) on July 26, 2022 (ECF No. 34-6). Then, Mr. Peka continued to have pain and difficulty moving his shoulder in the hours after, as evidenced by his inability to move his steering wheel with the left hand while driving. *Id*. Petitioner then had "classic shoulder issues" such as difficulty bathing. *Id*. at 72. In physical exams, Petitioner was noted to have warmth and redness at the site of the injection, indicating an immune

response. *Id*. at 77. Further, Dr. Natanzi noted, Petitioner recalled that the vaccination had appeared to be administered higher on his shoulder than in the past. A vaccine is "more likely to over-penetrate the intended target when you have a vaccine given too high." *Id*. at 75; G. Cross et al., *Don't Aim Too High: Avoiding Shoulder Injury Related to Vaccine Administration*, 45 Australian Family Physician 303, 303 (2016), filed as Ex. P18(c) (ECF No. 34-5).

Dr. Natanzi then discussed Petitioner's later physical exams and imaging. Petitioner initially displayed signs of shoulder impingement in a February 8, 2019 primary care exam, in which his physician noted pain with abduction. Tr. at 83. The MRI performed after this exam found bursal accumulation, and Dr. Natanzi explained that this accumulation coupled with shoulder impingement indicates bursitis. *Id*. at 84. Petitioner's August 28, 2019 exam was the first thorough orthopedic evaluation in Petitioner's record, according to Dr. Natanzi. *Id*. at 86. Petitioner displayed limited active ROM, but normal *passive* ROM.[3] Id. This ruled out frozen shoulder and capsulitis, which would impair passive ROM, but the active limitations suggested shoulder impingement. *Id*. at 86–87. Thus, Dr. Natanzi opined, "positive signs of impingement and subacromial bursal accumulation on the MRI, that lends itself to a diagnosis of bursitis, which is, I think, the hallmark SIRVA finding." *Id*. at 88.

Dr. Natanzi denied that the pre-vaccination records provided evidence of prior left shoulder injuries like the one Petitioner alleges occurred after the vaccine. Tr. at 67. He did acknowledge that Petitioner had deltoid pain in the past, but stated that it likely radiated from his damaged C5 nerve, and was thus "much different than what Mr. Peka experienced after." *Id*. at 68. When reviewing a set of x-rays from 2015, he noted that Petitioner had normal indicators for someone of his age, including degeneration of the acromioclavicular joint and rotator cuff calcification. *Id.* at 69. Further, Petitioner's shoulder had been x-rayed in the past after he reported difficulty turning his neck, and there were no findings that warranted follow-up. *Id*. at 67. There was no indication of issues in physical exams. *Id.*

Dr. Natanzi also expressed the opinion that Petitioner's left shoulder complaints were not associated with his cervical spine issues and radiculopathy, deeming the two to have "completely different isolated pathologies." Tr. at 68. To support this, he discussed differing clinical indicators in these injuries. For example, when undergoing a shoulder abduction test, patients with cervical radiculopathy often feel relief from pain when placing their hand on the crown of their head, because this movement helps release the pinched nerve in their neck. *Id*. at 73. Petitioner, by contrast, could not lift his arm up to shoulder height without pain—suggesting that his issues could not be explained by cervical radiculopathy. *Id.*

[3] Dr. Natanzi explained the difference between active and passive range of motion: "Actively means you do it yourself. Passively means that the examiner does it for you." Tr. at 87.

On cross, Dr. Natanzi acknowledged that Petitioner's records showed prior evidence of cervical radiculopathy and chronic degenerative changes. Tr. at 99–102. And there was evidence in these records of pre-vaccination existing left shoulder pain—although he attributed this to Petitioner's neck issues rather than any structures within the shoulder. *Id*. at 99, 102 (discussing Petitioner's February 2019 MRI showing both degenerative changes and bursal accumulation), 103 (discussing 2015 x-ray showing calcific tedinosis), 105–106 (discussing April 2018 chiropractic note documenting aching shoulders and pain radiating down arms). He disagreed with Respondent's counsel's contention that there were discrepancies between Petitioner's affidavit and testimony. *Id*. at 110. He stated that "[y]ou can differentiate between what we call nociceptive pain from—and neuropathic pain. Neuropathic pain is pain from nerves, which is stabbing, burning, electrical, shock-like versus the other pain which is more dull, achy." *Id.* The neuropathic pain Petitioner experienced is common for the spinal issues he had prior to vaccination. *Id.* at 112–13. Ultimately, Dr. Natanzi expressed the view that "100 percent" of Petitioner's post-vaccination shoulder issues were caused by the vaccine. *Id*. at 131.

In his rebuttal case, Dr. Natanzi reiterated that despite the November 15, 2018 treater note, it was not likely in his opinion that Petitioner's shoulder pain had resolved by that point. Tr. at 194, Ex. 3 at 65. He noted in this regard that the reference to improvement in symptoms was found in a different paragraph than the one referencing shoulder pain, leading him to conclude it did not reflect the view that the shoulder symptoms had subsided. *Id*. at 194. He also responded to the contention that Petitioner's diabetes explained his shoulder issues, stating that Petitioner's records revealed the diabetes to have been well-controlled. *Id*. at 195. And he deemed the August 28, 2019 orthopedic visit notes to be detained, and to clearly associate the onset of pain with the vaccination at issue. *Id*. at 196–97.

B. Respondent's Expert – Dr. Geoffrey D. Abrams, M.D.

Dr. Abrams, a board-certified orthopedic surgeon, prepared one written report for Respondent, opining therein that Petitioner cannot establish a causation-in-fact claim based on the record. Report, dated November 2, 2022, filed as Ex. A (ECF No. 37-1) ("Abrams Rep.").

Dr. Abrams received a Bachelor of Arts in Human Biology with a concentration in Neuroscience from Stanford University in 2000. *Curriculum Vitae,* filed as Ex. B on November 2, 2022 (ECF No. 37-11) ("Abrams CV") at 1; Abrams Rep. at 1. He received his medical degree from the University of California, San Diego. Abrams CV at 1. He completed a surgical internship at Stanford University in 2008. *Id*. Dr. Abrams completed his residency at Stanford University Hospital and Clinics in 2012, and a fellowship at Rush University Medical Center in 2013. *Id*. Dr. Abrams is board certified in Orthopedic Surgery, with a subspeciality in Orthopedic Sports Medicine. *Id.*; Abrams Rep. at 1. He is licensed to practice medicine in Illinois and California and is a California Fluoroscopy Supervisor and Operator. Abrams CV at 2. He holds academic

appointments at the Stanford University School of Medicine and the Veterans Administration Hospital of Palo Alto. *Id.* at 1; Abrams Rep. at 1. He serves as the head team physician for several of Stanford University's varsity teams, and is also an assistant team physician for the San Francisco 49ers. Abrams CV at 23; Abrams Rep. at 1.

Dr. Abrams opined that Petitioner may have spondylosis, or arthritis of the spine. Tr. at 136. Spondylosis can cause shoulder pain, neck pain, and pain in any of the upper extremities. *Id.* According to him, there is "absolutely" evidence of spondylosis in Petitioner's record. *Id*. at 138. To support this, he pointed to Petitioner's prior C3 to C7 fusions, and stated that "associated with these conditions is almost always arthritis of other areas of the spine." *Id*. He also pointed out that spondylosis can cause dull, aching shoulder pain like Petitioner experienced. *Id*. at 139. He contrasted this with the numbness and radiating pain associated with cervical radiculopathy. *Id*. However, he stated that either spondylosis or radiculopathy could have caused Petitioner's shoulder pain after vaccination. *Id*. at 140.

Dr. Abrams also pointed to other alternative explanations for the pain—like Petitioner's diabetes. Tr. at 141. Relying on a study cited in his report, he explained how diabetes can lead to shoulder pain—"[t]he sugars that leak out of the blood can attach to soft tissues and cause inflammation in various soft tissues of the body." Id., M. Brownlee, *Glycation Products and the Pathogenesis of Diabetic Complications,* 15 Diabetes Care 1835 (1992). He later referred to the leaked material as "advanced glycosylated end products." *Id*. at 143. He discussed several studies connecting diabetes and shoulder pathology and pain, and confirmed that the connections are "generally accepted in the medical community." *Id.* at 145. Another possible explanation, Dr. Abrams maintained, was Petitioner's rotator cuff pathology. *Id.* at 146.

Another factor weighing against a SIRVA, Dr. Abrams maintained, was the overall insufficient evidence in Petitioner's record of quick onset of limited range of motion, which is seen in the "great majority" of SIRVA cases. Tr. at 149. Medical literature, he maintained, establishes four days as the upper limit for onset, but in most cases it develops in a few hours. *Id*. But the *pain with motion* Petitioner described in the hours after his vaccination is not equivalent to SIRVA-associated ROM limitations. *Id*. at 150. He affirmed that medical records from visits on October 23 and 29, 2018, note normal range of motion. *Id.* at 150–151. It was only fairly long after—in August 2019—that treaters began to note ROM limits. *Id*. at 151. There was in Dr. Abrams's view a difference between active and passive ROM issues (*Id*. at 190–191)—and if Petitioner had a SIRVA injury, he should have displayed impaired passive range of motion in the shoulder that is not consistently present in his medical records. *Id*. at 192.

Dr. Abrams admitted otherwise that Petitioner had likely experienced some kind of vaccine reaction, but he deemed it consistent with a "superficial skin reaction, maybe a deeper myositis or

a little inflammation in the muscle." Tr. at 153. Thus, he concluded that any more serious shoulder pain Petitioner had was the result of his other conditions rather than a SIRVA. *Id.* at 154.

On cross, Dr. Abrams agreed that the October 2018 vaccination (the same month he began complaining of shoulder pain) was the only possible factor evident directly from the record that could be related to the pain (although as noted Dr. Abrams has proposed *other*, less-obvious explanations based on Petitioner's overall health). Tr. at 155–56. And he accepted that the vaccine was the likely cause of Petitioner's shoulder pain in the *immediate* short-term following vaccination. *Id.* at 158. However, he argued that sometime before his November 2018 primary visit, the cause of *subsequent* pain had likely shifted to something else. *Id*. Petitioner's pain immediately after vaccination could have been caused by myositis, cellulitis, or a more superficial injury – and this was distinguishable for Petitioner's more chronic pain complaints later. *Id.* at 181, 189.

To support this, he relied on the record of Petitioner's November 15, 2018 doctor visit. *Id*. at 160, Ex. 3 at 65. Although the note mentions Petitioner's shoulder pain, it goes on to discuss several other medical issues before stating "[i]n the interim, patient reports that his symptoms have improved"—and thus, in Dr. Abrams's view, the "spirit of the note" shows that the shoulder pain specifically had improved by that point. *Id*. at 161. He denied that this statement applied only to other issues detailed in the note, though he acknowledged that "there's a lot of other things discussed." *Id*. However, he conceded that notes for later visits included reports of shoulder pain, and Petitioner later "gets worked up for left shoulder injury, documented left shoulder abduction, restrictions, gets sent or an MRI, gets scheduled for an orthopedist" *Id*., at 162–63. Thus, Dr. Abrams allowed, it was possible that Petitioner's shoulder pain had in fact *not* resolved by November 2018. *Id.* at 165. And he also later agreed that subsequent treaters seemed to find Petitioner's comorbidities to be non-contributory for his ongoing shoulder pain, although he did not necessarily accept that all such treaters had sufficient expertise to so conclude, or had exhausted the possibility. *Id.* at 170–71.

III. Procedural History

After the case's initiation in August 2020, the matter was assigned to the "Special Processing Unit" ("SPU"), since it alleged a Table SIRVA claim of the kind that is routinely settled. But factual complexities got in the way of an amicable resolution, and the matter was transferred out of SPU in May 2022 (ECF No. 32), subsequently arriving on my own individual docket. Thereafter, both sides filed reports from the experts whose testimony is discussed above, and when that process was completed I set the matter for hearing, to be held in June 2023. Prehearing Order (ECF No. 39). The hearing occurred, the parties engaged in some post-hearing additional briefing, and the matter is now fully ripe for resolution.

IV. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[4] Petitioner alleges a Table and causation-in-fact claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

[4] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Each *Althen* prong requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." (citing *Moberly*, 592 F.3d at 1322)); *see also Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *appeal docketed,* No. 23-1816 (Fed. Cir. Apr. 28, 2023). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored

in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including

"any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which

compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are

> standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted, I

discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

ANALYSIS

I. Interplay Between Table and Non-Table Claims Based on Same Facts

It is not uncommon for the same facts relevant to an alleged vaccine injury to be the basis for both a Table and non-Table claim, such that the latter can viable even if the former is not. Indeed, in the SIRVA context in particular, I routinely find[5] (as here) that a Table element cannot be met, but then transfer the case out of SPU for resolution as a non-Table claim. At that point, however, the context for analysis changes substantively. The nature of the specific showing that must be met to obtain entitlement for a non-Table claim is quite different.

Causation is presumed for Table claims—meaning the Government has already made a determination, when announcing the existence of a Table claim, that sufficient scientific and medical evidence exists to allow Program claimants to seek damages without also requiring them to prove, for example, that a particular vaccine "can cause" an injury. In addition, Table claimants need only prove facts sufficient to meet certain elements of the claim at issue. *See* 42 C.F.R. § 100.3(b)(10). Most of the time, this obligates a petitioner to prove that (a) he received a covered vaccine, (b) he suffered a specific injury (consistent with the Table's "qualifications and aids to interpretation," which provide detailed definitions), and (c) the injury occurred in a defined timeframe measured from the time/date of vaccination. *Germaine v. Sec'y of Health & Hum. Servs.*, 155 Fed. Cl. 226, 227 (2021) (discussing the elements needed for compensation of a Table injury compared to those of a non-Table injury); *Spaans v. Sec'y of Dep't of Health & Hum. Servs.*, No. 12-585V, 2012 WL 5928730, at *1 (Fed. Cl. Spec. Mstr. Nov. 6, 2012) (dismissing a claim involving a non-covered vaccine).[6]

The specific Table elements relevant to a defined injury tend to be synergistically related, based on medical science about how (and when) a putative vaccine injury is *most likely* to occur.

[5] The Chief Special Master is responsible for adjudicating all SPU claims, and thus I have extensive familiarity with the elements of SIRVA claims.

[6] Sometimes expert input is required to adjudicate Table claims (for example, when a diagnosis is disputed), although it is not common.

SIRVA provides an excellent example. SIRVA is believed to occur almost *immediately* after the improper administration of a vaccine. G. Cross et al., *Don't Aim Too High: Avoiding Shoulder Injury Related to Vaccine Administration*, 45 Australian Family Physician 303, 303 (2016), filed as Ex. 9(c) (ECF No. 31-3). Thus, a Table SIRVA is only viable if preponderant evidence exists establishing pain very close in time to vaccination. However, while more often than not Table claimants allege immediate pain, a Table SIRVA can also succeed even if the pain does not manifest until up to 48 hours post-vaccination. The claim's most likely temporal "target" for occurrence, for purposes of the claim, has thus been widened somewhat. *See, e.g.*, National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 FR 45132-01 ("[i]n order to capture the broader array of potential injuries, the Secretary proposes to add SIRVA for all tetanus toxoid-containing vaccines that are administered intramuscularly through percutaneous injection into the upper arm. The interval of onset will be less than or equal to 48 hours").

Unsuccessful Table claims are not automatically dismissed in their entirety, even if it is determined that one or more Table elements cannot be met.[7] Nevertheless, thereafter the "road to entitlement" becomes more difficult (although the preponderant burden of proof is consistent) once the claim becomes subject to the non-Table, causation in fact analysis. Although non-Table claimants may often be able to take advantage of the evidence that resulted in the Table presumption in their effort to satisfy the first, "can cause" *Althen* prong,[8] they cannot rely on how close they came to meeting the Table requirements. *See, e.g.*, *Fantini v. Sec'y of Health & Hum. Servs.*, No. 15-1332V, 2022 WL 1760730, at *22 (Fed. Cl. Spec. Mstr. May 2, 2022) (". . . Program claimants cannot "piggyback" on the Table requirements when attempting to prove a non-Table claim."); *Greene v. Sec'y of Health & Hum. Servs.*, No. 11-631V, 2018 WL 3238611, at *9 (Fed. Cl. Spec. Mstr. May 7, 2018) (noting that an expert's opinion on the timing issue of a brachial neuritis claim relied on conclusory determinations that the "Table time periods were not that far off the time period in question (something Program law says is not permitted)"). Rather, they must support each prong with sufficient preponderant evidence.

[7] The failure of a Table claim would only result in a case's full dismissal if it was preponderantly established by the record evidence that *no* form of the claim could succeed. For example, flu vaccine/Guillain-Barré syndrome cases cannot succeed as Table claims when onset exceeds 42 days—but a case where onset was extremely long (say, three months) would not likely be entertained as a non-Table claim either, since special masters have almost never found onset to be medically acceptable outside of eight weeks/two months (and even that timeframe is not universally embraced among the special masters). *See, e.g.*, *Chinea v. Sec'y of Health & Human Servs.*, No. 15-095V, 2019 WL 1873322, at *33 (Fed. Cl. Mar. 15, 2019), *mot. for review den'd*, 144 Fed. Cl. 378 (2019) (finding that the onset of the petitioner's GBS occurred eleven to twelve weeks after her vaccination, well beyond the six- to eight-week medically appropriate timeframe for the occurrence of vaccine-induced GBS).

[8] *See* L.J. *v. Sec'y of Health & Hum. Servs.*, No. 17-0059V, 2021 WL 6845593, at *14 (Fed. Cl. Spec. Mstr. Dec. 2, 2021) ("[s]uch recognition by Respondent of the evidence supporting a causal link between vaccine and injury—since the very decision to add a claim reflects Respondent's determination that valid science supports revising the Table - has been held to support the establishment of the theory required by the first *Althen* prong").

II. Petitioner Cannot Establish All SIRVA Table Claim Elements

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying Qualifications and Aids to Interpretation ("QAI") are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (*e.g.* NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

Here, some Table elements are not met, and therefore the claim cannot succeed even if the majority of the elements are satisfied. In the "positive" column, Petitioner clearly has established 48-hour onset—in medical records from visits to treaters that occurred in the same month as vaccination, he complained of immediate pain; he never wavered in subsequent visits from stating

the same, or at least dating his pain as occurring "since" vaccination; and his credible testimony and witness statements are corroborative of that conclusion. In addition, his pain and ROM issues were limited to his left shoulder (despite other records detailing pain and issues elsewhere, which can be accounted for separately and appear unrelated to the SIRVA pain).

Whether Petitioner suffered ROM issues sufficient to meet the claim's requirements presents a closer question—although one I find can be determined in Petitioner's favor. Early on in Petitioner's post-vaccination history, there is virtually no record evidence that he was experiencing ROM limitations—and although Petitioner alleges he noticed this problem close-in-time to the vaccination (when driving away from his vaccine appointment), these contentions lack record corroboration. Later references to pain when Petitioner actively moved his arm are not the same as a *limitation in movement*, even if the latter is due to pain. However (albeit more than ten months post-vaccination), there is record evidence that Table-like ROM issues later arose for Petitioner in the late summer of 2019, and this evidence is enough to establish the existence of an ROM limitation, as required by the Table. A petitioner alleging a Table SIRVA need not establish ROM limitation *beginning* within 48 hours of vaccination (as he must with pain).[9]

However, there is *also* ample evidence of another "condition or abnormality" that would explain Petitioner's symptoms. Dr. Abram's testimony, and compelling reading of the record, does allow for the possibility *both* that other injuries (cervical radiculopathy or spondylosis) explain Petitioner's symptoms, or that they were caused by one of his comorbidities, like diabetes. Abrams Report at 5-7. Importantly, because of the Table's wording, I can find as a fact matter that Petitioner did not rebut this "possibility"—even though in the causation-in-fact setting, the construction of the Petitioner's burden would not require him to eliminate this same possibility. Here, to obtain the causality presumption, Petitioner must *affirmatively* satisfy the Table elements—one of which clearly requires him to *rule out* other explanations for his pain and related deficiencies. *See* 42 C.F.R. § 100.3(c)(10)(iv) ("No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy)." The bottom line is that ample record evidence exists – as reflected in MRI findings and amplified by Dr. Abrams—that *other things could explain* the shoulder pain Petitioner clearly experienced, and this is enough to defeat his Table showing.

III. Petitioner Has Shown Entitlement to Damages Under a Causation-in-Fact Claim

[9] Indeed, the claim's QAIs do not specify *any* particular timeframe in which ROM limits must manifest. And I do not otherwise find that a failure to show ROM manifesting within six months of onset implicates the Act's "severity requirement." *See* Section 11(c)(1)(D)(i). The Act only obligates a claimant to show that *sequelae* of the injury persisted more than six months from onset—and here that is easily demonstrated. It does not specify severity to mean that *all* manifestations of an injury, as defined by the QAIs, must fully be evident *within* six months of the onset. This is also not a case where no evidence of ROM issues is to be found (even if that is not the predominant character of Petitioner's SIRVA—something relevant to damages).

This case presents the relatively-uncommon circumstances in which a claim fails certain of the SIRVA Table elements, yet I can still find that a "non-Table" SIRVA has been established. This is a function both of the specific facts of this case, but also the manner in which the elements of a non-Table SIRVA claim vary from a Table claim. Here, the *Althen* prongs have been satisfied.)

I shall give very little time to the question of whether a vaccine "can cause" SIRVA. It is well-established that petitioners can "borrow" the evidence used by the Government to create a Table claim in attempting to prove a claim that cannot otherwise satisfy certain Table elements. *L.J. v. Sec'y of Health & Hum. Servs.*, No. 17-0059V, 2021 WL 6845593, at *14 (Fed. Cl. Spec. Mstr. Dec. 2, 2021). This reasonably flows from the fact that the Government only permits Table claims in the first place if it ascertains sufficient scientific or medical evidence to presume causation (albeit under certain fact circumstances). *See* 42 C.F.R. § 100.3(b)(10). And while the inability to meet some of those elements may mean a SIRVA is less likely, it does not mean that the "can cause" question must be wholly revisited, simply because the claim falls out of the Table otherwise. Here, there is more than enough proof to rely upon for me to conclude that misadministration of a vaccine can result in a SIRVA to find that the first *Althen* prong is met.

I also find (as noted above) that the third element, which involves whether onset occurred in a medically-acceptable timeframe, has been met. SIRVAs should occur fast, and did—here, this helps Petitioner on causation, since speed of onset makes SIRVA more likely. While Dr. Abrams contended that the initial reaction Petitioner had experienced was transient, resolving by mid-November 2018, the record clearly shows Petitioner did later continue to experience pain, to a sufficient degree that he sought treatment for it, and also associated it with the pain he had been experiencing since vaccination. I do not on this record find that Petitioner's pain had likely fully subsided in November.

This leaves only the second, "did cause" prong. And although it was hotly—and reasonably—disputed, and although both sides presented compelling expert testimony on the topic, I find in this case that the scales tip in Petitioner's favor. Respondent's strongest contentions against the second *Althen* prong arise from the evidence of alternative explanations—and even though Petitioners are never compelled to "disprove" other explanations, I do not find on this record that those the record establishes existed sufficiently undermine the conclusion that the vaccination was the more likely cause of Petitioner's symptoms. Known comorbidities, like diabetes or preexisting neck and spine issues, were either medically controlled or had not so significantly manifested as issues prior to vaccination. There is also some discernible treater support for vaccine association—along with an absence of contemporaneous treater views that Petitioner's other illnesses had caused his left shoulder complaints. And although Dr. Abrams is a well-qualified expert, in this case his efforts seemed more aimed at identifying plausible counter-

explanations than in connecting record proof of Petitioner's course to those explanations. The totality of evidence, when weighed collectively, favors Petitioner.

As I noted above, SIRVA claims may in some cases not prove tenable under the Table, and yet can be successful non-Table claims—depending on the mix of facts and expert testimony. I have in fact reached different conclusions even in cases involving *these same two experts*—underscoring the extent to which the record evidence ultimately matters most. *See,* e.g., *Bulman v. Sec'y of Health & Hum. Servs.*, No. 19-1217V, 2023 WL 5844348 (Fed. Cl. Spec. Mstr. Aug. 16, 2023) (denying entitlement in non-Table SIRVA case involving opinions from Drs. Natanzi and Abrams). Both sides relied on capable experts and made good faith, reasonable arguments—but here the facts supported Petitioner.

It is nevertheless unfortunate that so much time was spent disputing entitlement. Damages should not be nearly as difficult to resolve. Assuming Petitioner's out-of-pocket expenses are simple to calculate, the remainder of damages are likely limited to a modest pain and suffering award (since this is not a case involving surgery)—and I do not deem the Petitioner's somewhat intermittent course to favor a particularly large such award. I will thus expect these matters to be agreed upon within the first half of the year—or I will resolve them myself in that timeframe.

CONCLUSION

Petitioner has carried his burden of proof, and therefore is entitled to an award of damages. The parties shall contact chambers to set a status conference, at which time resolution of the damages phase of the action will be discussed.

IT IS SO ORDERED.

s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master